

Welch Allyn AED10 Trainer

User's Manual

Software Revision 01.01.xx

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Declaration of Conformity

Manufacturer: Medical Research Laboratories, Inc.,
A Welch Allyn Company
1000 Asbury Drive
Buffalo Grove, IL 60089 USA
Phone: (847) 520-0300
Fax: (847) 520-0303

European Office
Welch Allyn Ireland
Navan Business Park
Dublin Road, Navan, Co. Meath
Republic of Ireland
Phone: 011-353-466-7775
FAX: 011-353-462-7128

declares that the CE-marked product

Product Name: AED 10 Trainer
Accessories: As listed in User's Manual
Device Type: Accessory to Medical Device

complies with:

Council Directive 93/42/EEC (Medical Device Directive) of 14 June 1993 Annex II

class I (rule 1)

Safety: IEC 60601-1 / EN 60601-1 Internally Powered
IEC 60601-1-2 / EN 60601-1-2

Joel Orlinsky
Director of Q. A. and Regulatory Affairs

Date _____

Introducing the Welch Allyn AED10 Trainer

Overview

The Welch Allyn AED10 Trainer is a training tool for preparing emergency responders to use the Welch Allyn AED10 to treat a victim of sudden cardiac arrest. The Trainer provides realistic simulation of the Welch Allyn AED10 without actually charging or discharging electrical energy. Voice prompts, simulated energy delivery, pauses for CPR, training pads, and the functional system status indicator all accurately mimic the operation of the Welch Allyn AED10 and provide a realistic demonstration.

- ❖ Ten different scenarios are available.
- ❖ Multiple language selections are available.
- ❖ Hand held IR remote control allows instructors to customize training sessions.
- ❖ The Welch Allyn AED10 Trainer is intended for indoor use.
- ❖ The Welch Allyn AED10 Trainer is not intended to teach basic life-saving skills. Trainees should have completed an appropriate training class for knowledge in assessing the patient, CPR (cardiopulmonary resuscitation), and correct medical protocols.

Note: Training Pads should be used only with a “plastic skin” type mannequin. Do not use on foam-based mannequins.

Caution

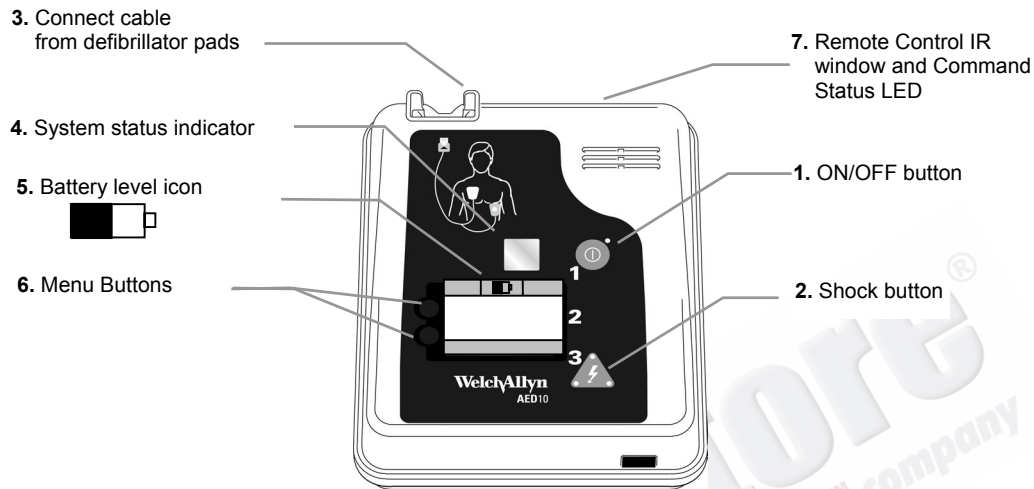
Trainer Pads are for demonstration purposes only and are not for clinical use.

Special Features

- ❖ Voice prompts identical to those in the Welch Allyn AED10.
- ❖ Text prompts identical to those in the Welch Allyn AED10.
- ❖ Remote control for instructor use.

Getting to Know the Welch Allyn AED10 Trainer

User Interface



1. **Green ON/OFF button.** Turns the unit on and off.
2. **Red Shock button.** Flashes to prompt a simulated shock, is pressed to deliver a simulated shock.
3. **ECG Pad Connector.** Connect cable from pads to the Trainer here.
4. **LCD Status Indicator.** Displays if the unit is ready for operation. A black diamond signifies the Trainer is ready for operation. A red circle with a line through it signifies a need to, replace the batteries, or service the unit. A flashing indicator or fading black diamond signifies low battery power; replace the batteries soon.
5. **Battery Level Icon.** Displays the current battery level. The Trainer will display text and voice prompts when the battery needs to be changed.
6. **Menu buttons.** Used to control volume, contrast, scenario, CPR timer, and language.
7. **Remote Control Window.** The Remote Control window allows light pulses from the Remote Control to be received. There is a Command Status LED located next to the Remote Control window which illuminates when a command is received.

Operating the Trainer

Trainer Mode

Trainer mode is the primary mode of operation and is accessed by pressing the green ON/OFF button. In this mode, the Menu buttons are inoperative and all menus are inactive. The ON/OFF button and the Shock button are the only user responsive buttons in this mode. While in Trainer mode the unit displays elapsed time, battery level, number of shocks delivered to the patient, text prompts, and various status messages on the LCD display.

Elapsed Time	Battery Level	Patient Shock Counter
AED Text		
Status		

Elapsed Time: While in Trainer mode the elapsed time is displayed in the upper left hand corner of the screen in the following format: HH:MM:SS. The Elapsed Time stops incrementing if the Trainer is paused during a scenario and continues after the scenario is resumed.

Battery Level: While in Trainer mode the Trainer graphically displays the battery level in the upper middle portion of the screen. The battery level indicator displays 10 distinct battery levels and is updated every second. The word "LOW" appears under the battery level symbol if the average battery voltage falls below operating levels.

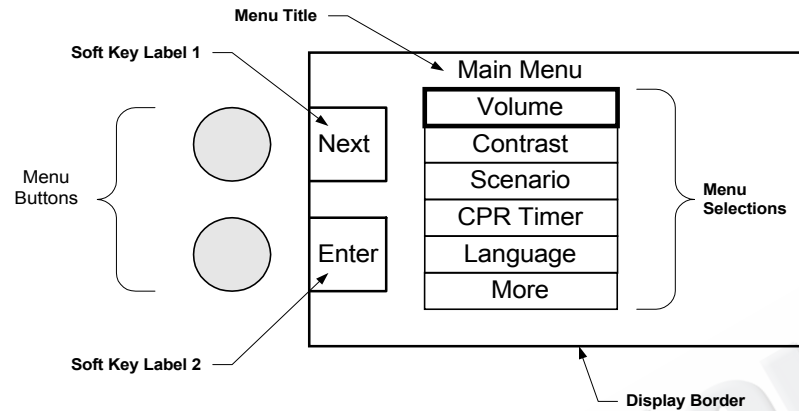
Patient Shock Counter: While in Trainer mode the unit displays the number of shocks delivered in the upper right hand corner of the screen

AED Text: While in Trainer mode this region of the display shows text prompts to the user.

Status: The lower right hand corner of the screen displays the simulated amount of delivered energy.

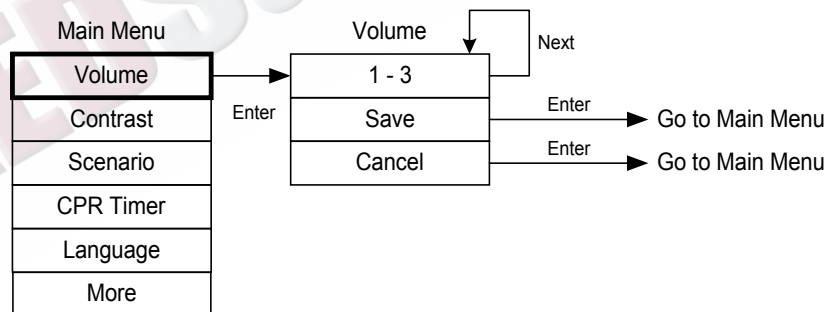
Menu Mode

Menu mode allows the user to access and set various system parameters. Menu mode is enabled by holding down the lower menu button while turning on the Trainer. Once the Trainer has been powered up into Menu mode, the following menu appears on the screen:



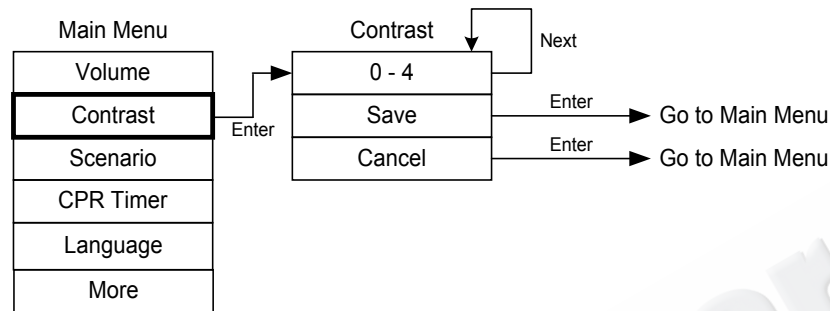
Volume

Pressing the Enter button while the Volume menu item is highlighted causes the Volume menu to be displayed, allowing the user to select a level between 1 and 3. As sound volume values are selected using the Next button, a beep is heard at the selected volume. The Save menu item saves the currently selected value and then returns to the Main Menu. The Cancel menu item restores the volume value that was present prior to entering the Volume menu and returns to the Main Menu.



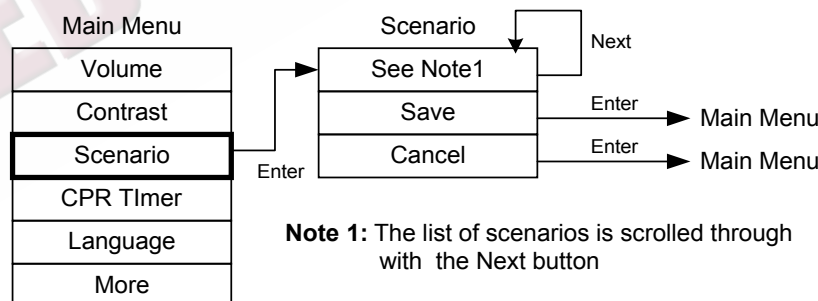
Contrast

Pressing the Enter button while the Contrast menu item is highlighted displays the Contrast menu, allowing the user to select a contrast value between 0 and 5. As contrast values are selected using the Next button, the display contrast changes immediately to the selected value. The Save menu item saves the currently selected value and returns to the Main Menu. The Cancel menu item restores the contrast value present prior to entering the Contrast menu and returns to the Main Menu.



Scenario

Pressing the Enter button while the Scenario menu item is highlighted displays the Scenario menu, allowing the user to select different scenarios (see “Scenarios” section for more details). Pressing the Next button causes a sequential display of possible Scenario numbers, and pressing the Enter button causes the current scenario number to be selected and the Save menu item to be highlighted. Pressing the Enter button while the Save menu item is highlighted stores the currently selected Scenario number and returns to the Main Menu. The Cancel menu item restores the scenario value present prior to entering the Scenario menu and returns to the Main Menu.

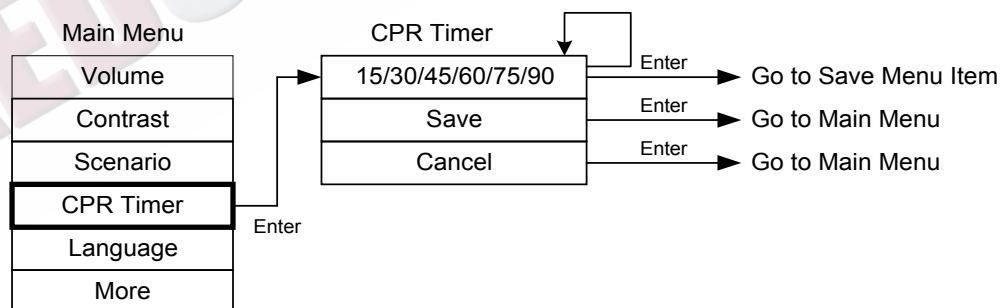


The scenarios are numbered sequentially in the same order as for the remote control.

Scenario	Description
1	AHA Scenario 1
2	AHA Scenario 2
3	AHA Scenario 3
4	AHA Scenario 4
5	AHA Scenario 5
6	AHA Scenario 6
7	AHA Scenario 7
8	AHA Scenario 8
9	Ventricular Fibrillation with one shock conversion
10	Ventricular Fibrillation with one shock conversion followed by refribrillation
11	Shockable Rhythm
12	Non-shockable Rhythm

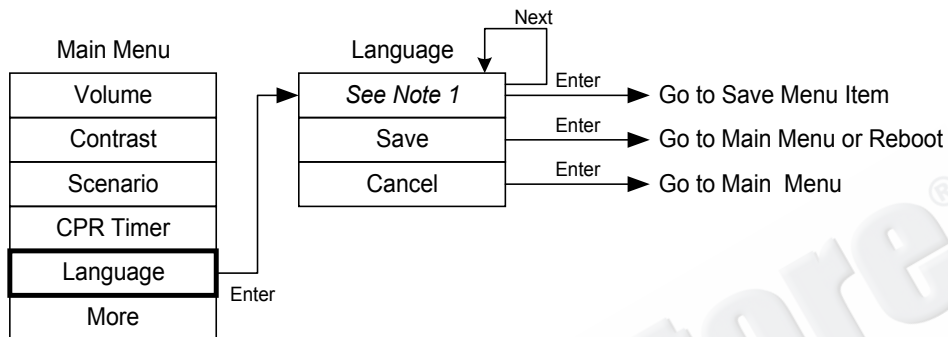
CPR Timer

Pressing the Enter button while the CPR menu item is highlighted displays the CPR menu, allowing the user to select a CPR time of 15, 30, 45, 60, 75, or 90 seconds. The Save menu item saves the currently selected value and returns to the Main Menu. The Cancel menu item restores the CPR time present prior to entering the CPR menu and returns to the Main Menu.



Language

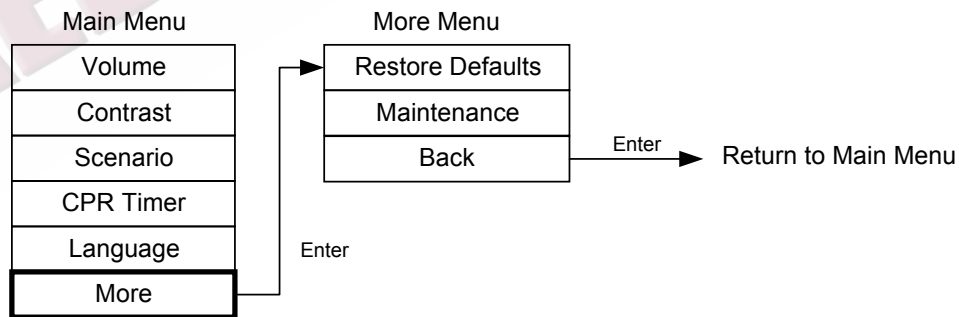
Pressing the Enter button while the Language menu item is highlighted causes the Language menu to be displayed. The current Language is displayed, and pressing the Next button scrolls through the list of available languages. Each language selection is displayed in its own language as the list is traversed, and pressing the Enter button while the Save menu item is highlighted stores the currently selected language as the new language parameter. All text is subsequently displayed in the new language. Pressing the Enter button while the Cancel menu item is highlighted displays the Main Menu.



Note: The Next button will scroll through the language list. Each language is displayed in its own language.

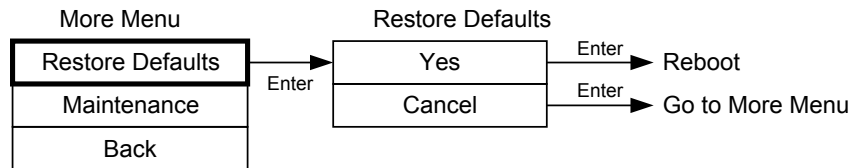
More

Pressing the Enter button while the More menu item is highlighted causes the More Menu to be displayed.



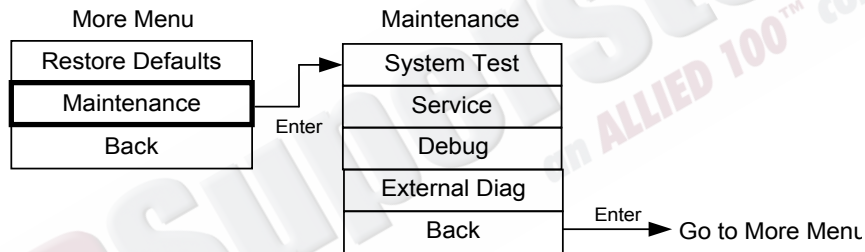
Restore Defaults

Pressing the Enter button while the Restore Default menu item is highlighted displays the restore defaults menu. Pressing the Next button scrolls down, highlighting the next menu item. If the Enter button is pressed while the Yes menu item is highlighted, all of the configuration parameters are forced to their default value except for the language. If the Enter button is pressed while the Cancel menu item is highlighted the More Menu is displayed.



Maintenance

Pressing the Enter button while the Maintenance menu item is highlighted displays the Maintenance Menu. This menu is for factory use only.



Scenarios

The Welch Allyn AED10 Trainer provides training scenarios that follow the American Heart Association (AHA) recommended AED training scenarios. These scenarios are pre-configured and give an AED Instructor a standard means of training and testing proficiency in AED use. Scenarios 1 to 10 may be selected with the Menu Mode Scenario menu or with the Remote Control. Scenarios 1 to 8 conform to the AHA recommended training scenarios. Scenario 9 is the same as AHA scenario 2 except with a one shock conversion. Scenario 10 is the same as AHA scenario 7 except with a one shock conversion followed by refrillation. See the following table of Training Scenarios.

The Scenario menu may also be used to select a continuous Shockable rhythm (11) or a continuous Non-shockable rhythm (12).

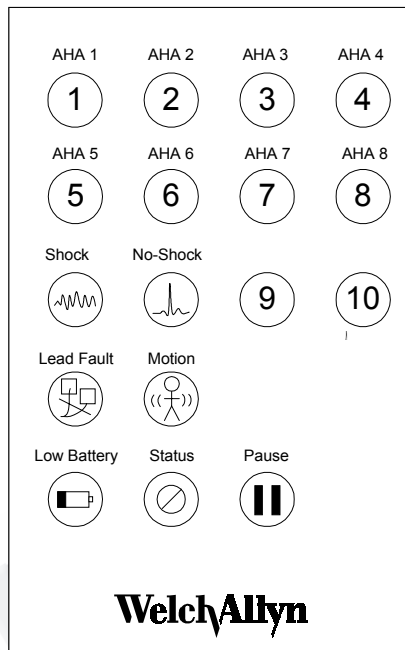
Scenario	Description	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6
1	Ventricular Fibrillation with four shock conversion	Shockable Rhythm	3 Shocks	CPR	Shockable Rhythm	1 Shock	Non-shockable Rhythm
2	Ventricular Fibrillation with two shock conversion	Shockable Rhythm	2 Shocks	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR
3	Ventricular Fibrillation with two shock conversion	Shockable Rhythm	2 Shocks	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR
4	Non-shockable Rhythm	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR
5	Ventricular Fibrillation with four shock conversion	Shockable Rhythm	3 Shocks	CPR	Shockable Rhythm	1 Shock	Non-shockable Rhythm
6	Non-shockable Rhythm	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR
7	Ventricular Fibrillation with two shock conversion followed by refribrillation	Shockable Rhythm	2 Shocks	Non-shockable Rhythm	Shockable Rhythm	1 Shock	Non-shockable Rhythm
8	Troubleshooting Skills Defibrillator Pads followed by two shock conversion	Pad Fault	Shockable Rhythm	2 Shocks	Non-shockable Rhythm	CPR	Non-shockable Rhythm
9	Ventricular Fibrillation with one shock conversion	Shockable Rhythm	1 Shock	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR
10	Ventricular Fibrillation with one shock conversion followed by refribrillation	Shockable Rhythm	1 Shock	Non-shockable Rhythm	Shockable Rhythm	1 Shock	Non-shockable Rhythm
11	Continuous Ventricular Fibrillation	Shockable Rhythm	3 Shocks	CPR	Shockable Rhythm	3 Shocks	CPR
12	Continuous Non-shockable Rhythm	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR	Non-shockable Rhythm	CPR

Changing the Batteries












1. Remove the four screws on the back panel.
2. Remove the panel.
3. Replace all batteries at the same time with 6 C-cell alkaline batteries. The status indicator will be flashing after battery replacement until the unit is powered on.
4. Replace the back panel and insert the four screws.

Remote Control (option)

The hand held remote control for the AED10 Trainer provides the Instructor with significant control over the configuration of the Trainer. The remote control communicates with the Trainer via an IR window located next to the pad's connector. A status indicator LED is located next to the IR window, and it will flash to indicate that a command has been received. The status indicator LED will flash continuously when a scenario has been paused. Refer to the diagram and descriptions listed below.



1	Allows the Instructor to select AHA Scenario number one as the default scenario (see table 2 for scenario descriptions). Trainer will automatically turn off after the selection has been made.	2	Allows the Instructor to select AHA Scenario number two as the default scenario. The Trainer will automatically turn off after the selection has been made.
3	Allows the Instructor to select AHA Scenario number three as the default scenario. The Trainer will automatically turn off after the selection has been made.	4	Allows the Instructor to select AHA Scenario number four as the default scenario. The Trainer will automatically turn off after the selection has been made.
5	Allows the Instructor to select AHA Scenario number five as the default scenario. The Trainer will automatically turn off after the selection has been made.	6	Allows the Instructor to select AHA Scenario number six as the default scenario. The Trainer will automatically turn off after the selection has been made.

	Allows the Instructor to select AHA Scenario number seven as the default scenario. The Trainer will automatically turn off after the selection has been made.		Allows the Instructor to select AHA Scenario number eight as the default scenario. The Trainer will automatically turn off after the selection has been made.
	Allows the Instructor to select Ventricular Fibrillation with one shock conversion. The Trainer will automatically turn off after the selection has been made.		Allows the Instructor to select Ventricular Fibrillation with one shock conversion followed by refibrillation. The Trainer will automatically turn off after the selection has been made.
	Allows Instructor to interrupt any scenario with a continuous shockable rhythm. The current default scenario is not changed.		Allows the Instructor to interrupt any scenario with a continuous non-shockable rhythm. The current default scenario is not changed.
	Allows the Instructor to interrupt any scenario with a lead fault condition. To resume the scenario, press the button again.		Allows the Instructor to interrupt any scenario with a "Motion" condition on the next rhythm analysis.
	Allows the Instructor to interrupt any scenario with a Low Battery condition. To resume the scenario, press the button again.		Allows the Instructor to simulate a Warning (flashing icon) system status. To resume the scenario, press the button again.
	Allows the Instructor to pause during any scenario. To resume the scenario, press the button again. Note: While the Trainer is paused, all other buttons are inactive until the pause button has been pressed again.		

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Appendix: Specifications

Physical Specifications

Batteries: 6 C-cell alkaline batteries

Battery life: approximately 40 hours

Number of training scenarios: Ten

Storage temperature (without batteries): -22° to 158°F (-30° to 70°C)

Operating temperature: 32° to 122°F (0° to 50°C)

Weight without batteries: 1.5 lbs

Weight with batteries: 2.5 lbs

Dimensions: 8 1/4" x 6 7/8" x 2 3/4" (210 x 175 x 70 mm)

Electromagnetic Compatibility

Category	Standard	Level
Radiated Emissions	EN55011	CISPR11 B
ESD	EN61000-4-2	8KV air 6KV contact
Radiated Susceptibility	EN61000-4-3	10 V/m (20 V/m EN 60601-2-4)

Guidance and Manufacturer's Declaration-Electromagnetic Emissions (IEC 60601-1-2 Table 201)

The Welch Allyn AED10 Trainer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED10 Trainer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Welch Allyn AED10 Trainer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CSPP 11	Class B	
Harmonic Emission IEC 6100-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (IEC 60601-1-2 Table 202)

The Welch Allyn AED10 Trainer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED10 Trainer should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode +/- 2 kV common mode	Not applicable Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (IEC 60601-1-2 Table 203)

The Welch Allyn AED10 Trainer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED10 Trainer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn AED10 Trainer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	Recommended separation distance $d = 1.17 \cdot \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	$d = 1.20 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.20 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.30 \cdot \sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^b

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.^d

Interference may occur in the vicinity of equipment marked with the following symbol:



Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- The ISM (industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Welch Allyn AED10 Trainer is used exceeds the applicable RF compliance level above, the Welch Allyn AED10 Trainer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Welch Allyn AED10 Trainer.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Welch Allyn AED10 Trainer (IEC 60601-1-2 Table 205)

The Welch Allyn AED10 Trainer is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn AED10 Trainer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn AED10 Trainer as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter				
m				
Rated maximum output power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = [^{3.5/3}] * \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [^{12/10}] * \sqrt{P}$	80 MHz to 800 MHz $d = [^{12/10}] * \sqrt{P}$	800MHz to 2.5 GHz $d = [^{23/10}] * \sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.3
10	3.69	3.79	3.79	7.27
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.